IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEUROCRINE BIOSCIENCES, INC. Plaintiff, v. CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD. and CRYSTAL PHARMATECH CO., LTD. Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Neurocrine Biosciences, Inc. ("Neurocrine"), by way of Complaint against Defendants Crystal Pharmaceutical (Suzhou) Co., Ltd. ("Crystal Suzhou") and Crystal Pharmatech Co., Ltd. ("Crystal Pharmatech") (collectively "Crystal" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,065,952 ("the '952 patent"), 10,844,058 ("the '058 patent"), 10,851,103 ("the '103 patent"), 10,851,104 ("the '104 patent"), 10,857,137 ("the '137 patent"), 10,857,148 ("the '148 patent"), 10,874,648 ("the '648 patent"), 10,906,902 ("the '902 patent"), 10,906,903 ("the '903 patent"), 10,912,771 ("the '771 patent"), 10,919,892 ("the '892 patent"), 10,940,141 ("the '141 patent") and 10,952,997 ("the '997 patent") (collectively, "patents-in-suit"), arising under the United States patent laws, Title 35 United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Crystal's filing of an Abbreviated New Drug Application ("ANDA") No. 215962 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell and/or sell

valbenazine tosylate capsules, equivalent to 40 mg and 80 mg of valbenazine base ("Crystal's generic products") before the expiration of the patents-in-suit.

THE PARTIES

2. Neurocrine is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 12780 El Camino Real, San Diego, CA 92130.

3. Neurocrine is engaged in the business of researching, developing and bringing to market innovative pharmaceutical products for the treatment of neurological, endocrine and psychiatric disorders.

4. Upon information and belief, Crystal Suzhou is a corporation organized under the laws of China and its principal place of business is located at B4-301, Biobay, 218 Xinghu Street, Suzhou Industrial Park, China, 215123.

5. Upon information and belief, Crystal Pharmatech is a corporation organized under the laws of China and its principal place of business is located at Suite 427, Bldg A2, Biobay 218 Xinghu Street, Suzhou Industrial Park, Suzhou, Jiangsu Province, 215123, China.

6. Upon information and belief, Crystal Suzhou is a wholly-owned subsidiary of Crystal Pharmatech.

7. Upon information and belief, Crystal Suzhou and Crystal Pharmatech are generic pharmaceutical companies that, in coordination with each other or at the direction of Crystal Pharmatech, develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Crystal Suzhou. Upon information and belief, Crystal Suzhou is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Crystal Suzhou directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Crystal Suzhou purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Crystal's generic products.

10. This Court has personal jurisdiction over Crystal Pharmatech. Upon information and belief, Crystal Pharmatech is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Crystal Pharmatech directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Crystal Pharmatech purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Crystal's generic products.

11. Upon information and belief, Crystal Suzhou states that it focuses on "development of novel polymorph APIs and high barrier-to-entry generic products and collaborating with API manufacturers and generic companies to launch generic drugs as early as possible" and "development of FTF ANDAs with polymorph and formulation barrier." https://www.linkedin.com/company/crystal-pharmaceutical-suzhou-co-ltd/about/ (accessed July 21, 2021).

12. Upon information and belief, Crystal Suzhou is the holder of FDA Drug Master File No. 35195 for valbenazine tosylate.

13. Upon information and belief, Crystal Suzhou and Crystal Pharmatech hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

14. Upon information and belief, Crystal admits that it has an established generic presence in the United States, having "[s]upported 8 FTF (first-to-file) ANDAs containing Paragraph IV Certification using novel polymorphs." https://www.linkedin.com/company/crystal-pharmaceutical-suzhou-co-ltd/about/ (accessed July 21, 2021). Upon information and belief, Crystal has at least one research and development facility in the United States. *Id.* (accessed July 21, 2021).

15. Crystal's ANDA filing regarding the patents-in-suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Crystal's intent to market and sell Crystal's generic products in this judicial district.

16. Crystal has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Crystal intends to direct sales of its generic drugs in this judicial district, among other places, once Crystal receives the requested FDA approval to market its generic products. Upon information and belief, Crystal will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

17. Upon information and belief, Crystal Suzhou and Crystal Pharmatech have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 215962.

18. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiciton over Crystal.

19. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Crystal Suzhou is incorporated in China and may be sued in any judicial district in the United States.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Crystal Pharmatech is incorporated in China and may be sued in any judicial district in the United States.

FACTUAL BACKGROUND

The NDA

21. Neurocrine is the holder of New Drug Application ("NDA") No. 209241 for INGREZZA® (valbenazine) Capsules in 40, 60, and 80 mg dosage forms ("INGREZZA® Capsules").

22. The FDA approved NDA No. 209241 on April 11, 2017.

23. INGREZZA® Capsules are prescription drugs approved for the treatment of tardive dyskinesia. Valbenazine, which is present as the tosylate salt, is the active ingredient in INGREZZA® Capsules.

24. Valbenazine Capsules are marketed in the United States under the trademark INGREZZA®.

The Patents-in-Suit

25. The United States Patent and Trademark Office ("the PTO") issued the '952 patent on September 4, 2018, titled "Valbenazine Salts and Polymorphs Thereof." A true and correct copy of the '952 patent is attached as Exhibit A.

26. Neurocrine owns the '952 patent through assignment as recorded by the PTO at Reel 041075, Frame 0820 and Reel 042510, Frame 0992.

27. The '952 patent currently expires on October 28, 2036.

28. The '952 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 209241 for INGREZZA® Capsules.

29. The PTO issued the '058 patent on November 24, 2020, titled "Valbenazine Salts and Polymorphs Thereof." A true and correct copy of the '058 patent is attached as Exhibit B.

30. Neurocrine owns the '058 patent through assignment as recorded by the PTO at Reel 052974, Frame 0121; Reel 052974, Frame 0549 and Reel 053995, Frame 0827.

31. The '058 patent currently expires on October 28, 2036.

32. The '058 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

33. The PTO issued the '103 patent on December 1, 2020, titled "Valbenazine Salts and Polymorphs Thereof." A true and correct copy of the '103 patent is attached as Exhibit C.

34. Neurocrine owns the '103 patent through assignment as recorded by the PTO at Reel 052974, Frame 0121; Reel 052974, Frame 0549 and Reel 053995, Frame 0827.

35. The '103 patent currently expires on October 28, 2036.

36. The '103 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

37. The PTO issued the '104 patent on December 1, 2020, titled "Valbenazine Salts and Polymorphs Thereof." A true and correct copy of the '104 patent is attached as Exhibit D.

38. Neurocrine owns the '104 patent through assignment as recorded by the PTO at Reel 052974, Frame 0121; Reel 052974, Frame 0549 and Reel 053995, Frame 0827.

39. The ’104 patent currently expires on October 28, 2036.

40. The ’104 patent is listed the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

41. The PTO issued the ’137 patent on December 8, 2020, titled “Methods for the Administration of Certain VMAT2 Inhibitors.” A true and correct copy of the ’137 patent is attached as Exhibit E.

42. Neurocrine owns the ’137 patent through assignment as recorded by the PTO at Reel 052974, Frame 0888.

43. The ’137 patent currently expires on October 10, 2037.

44. The ’137 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

45. The PTO issued the ’148 patent on December 8, 2020, titled “Methods for the Administration of Certain VMAT2 Inhibitors.” A true and correct copy of the ’148 patent is attached as Exhibit F.

46. Neurocrine owns the ’148 patent through assignment as recorded by the PTO at Reel 053415, Frame 0436.

47. The ’148 patent currently expires on October 10, 2037.

48. The ’148 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

49. The PTO issued the ’648 patent on December 29, 2020, titled “Methods for the Administration of Certain VMAT2 Inhibitors.” A true and correct copy of the ’648 patent is attached as Exhibit G.

50. Neurocrine owns the ’648 patent through assignment as recorded by the PTO at Reel 050397, Frame 0502 and Reel 050515, Frame 0577.

51. The ’648 patent currently expires on October 10, 2037.

52. The ’648 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

53. The PTO issued the ’902 patent on February 2, 2021, titled “Synthetic Methods for Preparation of (*S*)-(2*R*,3*R*,11b*R*)-3-isobutyl-9,10-dimethoxy-2,3,4,6,7,11b-hexahydro-1H-pyrido[2,1-a]isoquinolin-2- 2-amino-3-methylbutanoate di(4-methylbenzenesulfonate).” A true and correct copy of the ’902 patent is attached as Exhibit H.

54. Neurocrine owns the ’902 patent through assignment as recorded by the PTO at Reel 053426, Frame 0765; Reel 053426, Frame 0633; Reel 053440, Frame 0795 and Reel 053800, Frame 0270.

55. The ’902 patent currently expires on December 22, 2036.

56. The ’902 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

57. The PTO issued the ’903 patent on February 2, 2021, titled “Synthetic Methods for Preparation of (*S*)-(2*R*,3*R*,11b*R*)-3-isobutyl-9,10-dimethoxy-2,3,4,6,7,11b-hexahydro-1H-pyrido[2,1 -a]isoquinolin-2-yl 2-amino-3-methylbutanoate di(4-methylbenzenesulfonate).” A true and correct copy of the ’903 patent is attached as Exhibit I.

58. Neurocrine owns the ’903 patent through assignment as recorded by the PTO at Reel 053426, Frame 0765; Reel 053426, Frame 0633; Reel 053440, Frame 0795 and Reel 053800, Frame 0270.

59. The ’903 patent currently expires on December 22, 2036.

60. The ’903 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

61. The PTO issued the ’771 patent on February 9, 2021, titled “Methods for the Administration of Certain VMAT2 Inhibitors.” A true and correct copy of the ’771 patent is attached as Exhibit J.

62. Neurocrine owns the ’771 patent through assignment as recorded by the PTO at Reel 054349, Frame 0110.

63. The ’771 patent currently expires on October 10, 2037.

64. The ’771 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

65. The PTO issued the ’892 patent on February 16, 2021, entitled “Synthetic Methods for Preparation of (*S*)-(2*R*,3*R*,11b*R*)-3-isobutyl-9,10-dimethoxy-2,3,4,6,7,11b-hexahydro-1H-pyrido[2,1-a]isoquinolin-2-yl 2-amino-3-methylbutanoate di(4-methylbenzenesulfonate).” A true and correct copy of the ’892 patent is attached as Exhibit K.

66. Neurocrine owns the ’892 patent through assignment as recorded by the PTO at Reel 053426, Frame 0765; Reel 053426, Frame 0633; Reel 053440, Frame 0795 and Reel 053800, Frame 0270.

67. The ’892 patent currently expires on December 22, 2036.

68. The ’892 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

69. The PTO issued the ’141 patent on March 9, 2021, titled “Methods for the Administration of Certain VMAT2 Inhibitors.” A true and correct copy of the ’141 patent is attached as Exhibit L.

70. Neurocrine owns the '141 patent through assignment as recorded by the PTO at Reel 053540, Frame 0438.

71. The '141 patent currently expires on August 10, 2040.

72. The '141 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

73. The PTO issued the '997 patent on March 23, 2021, titled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '997 patent is attached as Exhibit M.

74. Neurocrine owns the '997 patent through assignment as recorded by the PTO at Reel 052974, Frame 0968.

75. The '997 patent currently expires on October 10, 2037.

76. The '997 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

The ANDA

77. Upon information and belief, Crystal submitted ANDA No. 215962 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, import, offer to sell and/or sell in the United States valbenazine tosylate capsules, equivalent to 40 mg and 80 mg of valbenazine base (defined above as "Crystal's generic products"), which are generic versions of Neurocrine's INGREZZA® Capsules.

78. Neurocrine received a letter from Crystal dated June 9, 2021 ("Crystal's First Notice Letter"), purporting to include "Crystal Pharmaceutical (Suzhou) Co. Ltd.'s Detailed Statement of the Factual and Legal Bases that [the patents-in-suit], Identified in the FDA's Orange Book for INGREZZA® (Valbenazine) Capsules Is Invalid, Unenforceable, and/or Not Infringed

by the Manufacture, Use or Sale of Crystal Pharmaceutical (Suzhou) Co. Ltd.'s Valbenazine Capsules." Crystal defined "Crystal" as "Crystal Pharmaceutical (Suzhou) Co. Ltd." Upon information and belief, Crystal Pharmaceutical (Suzhou) Co. Ltd. is the same entity as Crystal Pharmaceutical (Suzhou) Co., Ltd. Crystal's First Notice Letter identifies "Crystal's ANDA 215962 for valbenazine tosylate capsules, equivalent to 40 mg of valbenazine base" and states that "[t]he drug product that is the subject of Crystal's ANDA No. 215962 is valbenazine, which is provided as 73 mg of valbenazine ditosylate. equivalent to 40 mg of valbenazine free base." Crystal's First Notice Letter does not identify any other proposed ANDA drug products and did not mention Neurocrine's 80 mg INGREZZA® (valbenazine) capsules. Additionally, Crystal's First Notice Letter does not identify the patent number and expiration date for the '903 patent in the list of patents for which "ANDA 215962 contains the required bioavailability and/or bioequivalence data and a Paragraph IV Certification," but also states "that Crystal submitted to the [FDA] an Abbreviated New Drug Application No. 215962 for valbenazine capsules, 40 mg . . . containing a Paragraph IV certification with respect to U.S. Patent Nos. 10,065,952; 10,844,058; 10,851,103; 10,851,104; 10,857,137; 10,857,148; 10,874,648; 10,906,902; 10,906,903; 10,912,771; 10,919,892; 10,940,141; and 10,952,997."

79. Neurocrine received a second letter from Crystal dated June 11, 2021 ("Crystal's Second Notice Letter"), purporting to include "Crystal Pharmaceutical (Suzhou) Co. Ltd.'s Detailed Statement of the Factual and Legal Bases that [the patents-in-suit], Identified in the FDA's Orange Book for INGREZZA® (Valbenazine) Capsules Is Invalid, Unenforceable, and/or Not Infringed by the Manufacture, Use or Sale of Crystal Pharmaceutical (Suzhou) Co. Ltd.'s Valbenazine Capsules." Crystal defined "Crystal" as "Crystal Pharmaceutical (Suzhou) Co. Ltd." Upon information and belief, Crystal Pharmaceutical (Suzhou) Co. Ltd. is the same entity as

Crystal Pharmaceutical (Suzhou) Co., Ltd. Crystal's Second Notice Letter identifies "Crystal's ANDA 215962 for valbenazine tosylate capsules, equivalent to 40 mg and 80 mg of valbenazine base" and states that "[t]he drug product that is the subject of Crystal's ANDA No. 215962 is valbenazine, which is provided as 73 mg and 146 mg of valbenazine ditosylate, equivalent to 40 mg and 80 mg of valbenazine free base, respectively." Additionally, Crystal's Second Notice Letter identifies the patent number and expiration date for the '903 patent in the list of patents for which "ANDA 215962 contains the required bioavailability and/or bioequivalence data and a Paragraph IV Certification," and states "that Crystal submitted to the [FDA] an Abbreviated New Drug Application No. 215962 for valbenazine capsules, 40 mg and 80 mg. . . containing a Paragraph IV certification with respect to U.S. Patent Nos. 10,065,952; 10,844,058; 10,851,103; 10,851,104; 10,857,137; 10,857,148; 10,874,648; 10,906,902; 10,906,903; 10,912,771; 10,919,892; 10,940,141; and 10,952,997."

80. Crystal's First Notice Letter and Crystal's Second Notice Letter (collectively, "Crystal's Notice Letters") state that ANDA No. 215962 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the patents-in-suit are invalid, unenforceable or will not be infringed by the manufacture, use, sale, offer for sale or importation of Crystal's generic products.

81. Plaintiff commenced this action within 45 days of receiving Crystal's Notice Letters.

COUNT I

(INFRINGEMENT OF THE '952 PATENT)

82. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

83. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '952 patent.

84. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '952 patent are invalid, unenforceable and/or will not be infringed.

85. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

86. Crystal has actual knowledge of the '952 patent, as evidenced by Crystal's Notice Letters.

87. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '952 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '952 patent.

88. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

89. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '952 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing

to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215962 shall be no earlier than the expiration of the '952 patent.

90. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '952 patent.

91. Upon information and belief, Crystal has knowledge of the '952 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '952 patent, either literally or under the doctrine of equivalents.

92. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '952 patent.

93. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

94. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

95. Plaintiff does not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '058 PATENT)

96. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

97. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '058 patent.

98. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '058 patent are invalid, unenforceable and/or will not be infringed.

99. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

100. Crystal has actual knowledge of the '058 patent, as evidenced by Crystal's Notice Letters.

101. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '058 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '058 patent.

102. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

103. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '058 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 215962 shall be no earlier than the expiration of the '058 patent and any additional periods of exclusivity.

104. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '058 patent.

105. Upon information and belief, Crystal has knowledge of the '058 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '058 patent, either literally or under the doctrine of equivalents.

106. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '058 patent.

107. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

108. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

109. Plaintiff does not have an adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '103 PATENT)

110. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

111. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '103 patent.

112. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '103 patent are invalid, unenforceable and/or will not be infringed.

113. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

114. Crystal has actual knowledge of the '103 patent, as evidenced by Crystal's Letters.

115. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '103 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '103 patent.

116. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

117. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '103 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 215962 shall be no earlier than the expiration of the '103 patent and any additional periods of exclusivity.

118. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '103 patent.

119. Upon information and belief, Crystal has knowledge of the '103 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '103 patent, either literally or under the doctrine of equivalents.

120. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '103 patent.

121. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

122. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

123. Plaintiff does not have an adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '104 PATENT)

124. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

125. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '104 patent.

126. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '104 patent are invalid, unenforceable and/or will not be infringed.

127. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

128. Crystal has actual knowledge of the '104 patent, as evidenced by Crystal's Notice Letters.

129. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '104 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '104 patent.

130. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

131. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '104 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 215962 shall be no earlier than the expiration of the '104 patent and any additional periods of exclusivity.

132. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '104 patent.

133. Upon information and belief, Crystal has knowledge of the '104 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '104 patent, either literally or under the doctrine of equivalents.

134. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '104 patent.

135. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

136. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

137. Plaintiff does not have an adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '137 PATENT)

138. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

139. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '137 patent.

140. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '137 patent are invalid, unenforceable and/or will not be infringed.

141. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

142. Crystal has actual knowledge of the '137 patent, as evidenced by Crystal's Notice Letters.

143. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '137 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '137 patent.

144. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

145. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '137 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 215962 shall be no earlier than the expiration of the '137 patent and any additional periods of exclusivity.

146. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '137 patent.

147. Upon information and belief, Crystal has knowledge of the '137 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '137 patent, either literally or under the doctrine of equivalents.

148. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '137 patent.

149. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

150. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

151. Plaintiff does not have an adequate remedy at law.

COUNT VI

(INFRINGEMENT OF THE '148 PATENT)

152. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

153. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '148 patent.

154. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '148 patent are invalid, unenforceable and/or will not be infringed.

155. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

156. Crystal has actual knowledge of the '148 patent, as evidenced by Crystal's Notice Letters.

157. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '148 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '148 patent.

158. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

159. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '148 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 215962 shall be no earlier than the expiration of the '148 patent and any additional periods of exclusivity.

160. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '148 patent.

161. Upon information and belief, Crystal has knowledge of the '148 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '148 patent, either literally or under the doctrine of equivalents.

162. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '148 patent.

163. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

164. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

165. Plaintiff does not have an adequate remedy at law.

COUNT VII

(INFRINGEMENT OF THE '648 PATENT)

166. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

167. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '648 patent.

168. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '648 patent are invalid, unenforceable and/or will not be infringed.

169. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

170. Crystal has actual knowledge of the '648 patent, as evidenced by Crystal's Notice Letters.

171. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '648 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '648 patent.

172. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

173. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '648 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 215962 shall be no earlier than the expiration of the '648 patent and any additional periods of exclusivity.

174. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '648 patent.

175. Upon information and belief, Crystal has knowledge of the '648 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '648 patent, either literally or under the doctrine of equivalents.

176. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '648 patent.

177. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

178. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

179. Plaintiff does not have an adequate remedy at law.

COUNT VIII

(INFRINGEMENT OF THE '902 PATENT)

180. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

181. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '902 patent.

182. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '902 patent are invalid, unenforceable and/or will not be infringed.

183. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

184. Crystal has actual knowledge of the '902 patent, as evidenced by Crystal's Notice Letters.

185. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '902 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '902 patent.

186. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

187. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe at least one claim of the '902 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA

approval of ANDA No. 215962 shall be no earlier than the expiration of the '902 patent and any additional periods of exclusivity.

188. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

189. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

190. Plaintiff does not have an adequate remedy at law.

COUNT IX

(INFRINGEMENT OF THE '903 PATENT)

191. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

192. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '903 patent.

193. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '903 patent are invalid, unenforceable and/or will not be infringed.

194. Upon information and belief, Crystal admits infringement of at least one claim of the '903 patent because Crystal's Notice Letters did not provide any non-infringement allegation with respect to at least one claim of the '903 patent.

195. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

196. Crystal has actual knowledge of the '903 patent, as evidenced by Crystal's Notice Letters.

197. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '903 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '903 patent.

198. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

199. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe at least one claim of the '903 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215962 shall be no earlier than the expiration of the '903 patent and any additional periods of exclusivity.

200. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

201. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

202. Plaintiff does not have an adequate remedy at law.

COUNT X

(INFRINGEMENT OF THE '771 PATENT)

203. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

204. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '771 patent.

205. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '771 patent are invalid, unenforceable and/or will not be infringed.

206. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

207. Crystal has actual knowledge of the '771 patent, as evidenced by Crystal's Notice Letters.

208. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '771 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '771 patent.

209. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

210. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '771 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic

products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215962 shall be no earlier than the expiration of the '771 patent and any additional periods of exclusivity.

211. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '771 patent.

212. Upon information and belief, Crystal has knowledge of the '771 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '771 patent, either literally or under the doctrine of equivalents.

213. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '771 patent.

214. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

215. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

216. Plaintiff does not have an adequate remedy at law.

COUNT XI

(INFRINGEMENT OF THE '892 PATENT)

217. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

218. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '892 patent.

219. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '892 patent are invalid, unenforceable and/or will not be infringed.

220. Upon information and belief, Crystal admits infringement of at least one claim of the '892 patent because Crystal's Notice Letters did not provide any non-infringement allegation with respect to at least one claim of the '892 patent.

221. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

222. Crystal has actual knowledge of the '892 patent, as evidenced by Crystal's Notice Letters.

223. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '892 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '892 patent.

224. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

225. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe at least one claim of the '892 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215962 shall be no earlier than the expiration of the '892 patent and any additional periods of exclusivity.

226. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

227. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

228. Plaintiff does not have an adequate remedy at law.

COUNT XII

(INFRINGEMENT OF THE '141 PATENT)

229. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

230. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '141 patent.

231. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '141 patent are invalid, unenforceable and/or will not be infringed.

232. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

233. Crystal has actual knowledge of the '141 patent, as evidenced by Crystal's Notice Letters.

234. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '141 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '141 patent.

235. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

236. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '141 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215962 shall be no earlier than the expiration of the '141 patent and any additional periods of exclusivity.

237. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '141 patent.

238. Upon information and belief, Crystal has knowledge of the '141 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '141 patent, either literally or under the doctrine of equivalents.

239. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '141 patent.

240. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

241. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

242. Plaintiff does not have an adequate remedy at law.

COUNT XIII

(INFRINGEMENT OF THE '997 PATENT)

243. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

244. Upon information and belief, Crystal filed ANDA No. 215962 seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '997 patent.

245. Crystal's Notice Letters state that Crystal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '997 patent are invalid, unenforceable and/or will not be infringed.

246. Upon information and belief, in its ANDA No. 215962, Crystal has represented to the FDA that Crystal's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

247. Crystal has actual knowledge of the '997 patent, as evidenced by Crystal's Notice Letters.

248. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Crystal has infringed at least one claim of the '997 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215962, seeking approval to manufacture, use, import, offer to sell or sell Crystal's generic products before the expiration date of the '997 patent.

249. Upon information and belief, if ANDA No. 215962 is approved, Crystal intends to and will manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States.

250. Upon information and belief, if ANDA No. 215962 is approved, Crystal will infringe one or more claims of the '997 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Crystal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215962 shall be no earlier than the expiration of the '997 patent and any additional periods of exclusivity.

251. Upon information and belief, Crystal knows, should know and intends that physicians will prescribe and patients will take Crystal's generic products for which approval is sought in ANDA No. 215962, and therefore will infringe at least one claim of the '997 patent.

252. Upon information and belief, Crystal has knowledge of the '997 patent and, by its proposed package insert for Crystal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '997 patent, either literally or under the doctrine of equivalents.

253. Upon information and belief, Crystal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Crystal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '997 patent.

254. Upon information and belief, Crystal's actions relating to Crystal's ANDA No. 215962 complained of herein were done by and for the benefit of Crystal.

255. Plaintiff will be irreparably harmed by Crystal's infringing activities unless this Court enjoins those activities.

256. Plaintiff does not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '952 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '952 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the

expiration of the ’952 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the ’952 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Crystal’s generic products shall be no earlier than the expiration date of the ’952 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal’s generic products within the United States, or importing Crystal’s generic products into the United States, until the expiration of the ’952 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the ’952 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the ’058 patent through Crystal’s submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal’s generic products in the United States before the expiration of the ’058 patent;

G. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal’s making, using, offering to sell, selling or importing of Crystal’s generic products before the expiration of the ’058 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the ’058 patent under 35 U.S.C. § 271(a), (b) and/or (c);

H. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '058 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

I. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '058 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

J. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '058 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

K. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '103 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '103 patent;

L. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '103 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '103 patent under 35 U.S.C. § 271(a), (b) and/or (c);

M. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '103 patent and any additional

periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

N. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '103 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

O. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '103 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

P. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '104 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '104 patent;

Q. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '104 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '104 patent under 35 U.S.C. § 271(a), (b) and/or (c);

R. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '104 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

S. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '104 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

T. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '104 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

U. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '137 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '137 patent;

V. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '137 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '137 patent under 35 U.S.C. § 271(a), (b) and/or (c);

W. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '137 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

X. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling

Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '137 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Y. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '137 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Z. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '148 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '148 patent;

AA. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '148 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '148 patent under 35 U.S.C. § 271(a), (b) and/or (c);

BB. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '148 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

CC. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into

the United States, until the expiration of the '148 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

DD. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '148 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

EE. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '648 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '648 patent;

FF. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '648 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '648 patent under 35 U.S.C. § 271(a), (b) and/or (c);

GG. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '648 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

HH. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '648 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

II. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '648 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

JJ. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '902 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '902 patent;

KK. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '902 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '902 patent under 35 U.S.C. § 271(a), (b) and/or (c);

LL. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '902 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

MM. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '902 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

NN. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the

ANDA until the expiration of the '902 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

OO. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '903 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '903 patent;

PP. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '903 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '903 patent under 35 U.S.C. § 271(a), (b) and/or (c);

QQ. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '903 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

RR. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '903 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

SS. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '903 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

TT. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '771 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '771 patent;

UU. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '771 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '771 patent under 35 U.S.C. § 271(a), (b) and/or (c);

VV. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '771 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

WW. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '771 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

XX. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '771 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

YY. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '892 patent through Crystal's submission of ANDA No. 215962 to the FDA

seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '892 patent;

ZZ. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '892 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '892 patent under 35 U.S.C. § 271(a), (b) and/or (c);

AAA. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '892 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

BBB. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '892 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

CCC. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '892 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

DDD. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '141 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '141 patent;

EEE. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the expiration of the '141 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '141 patent under 35 U.S.C. § 271(a), (b) and/or (c);

FFF. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '141 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

GGG. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '141 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

HHH. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '141 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

III. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Crystal has infringed at least one claim of the '997 patent through Crystal's submission of ANDA No. 215962 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Crystal's generic products in the United States before the expiration of the '997 patent;

JJJ. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Crystal's making, using, offering to sell, selling or importing of Crystal's generic products before the

expiration of the '997 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '997 patent under 35 U.S.C. § 271(a), (b) and/or (c);

KKK. The issuance of an order that the effective date of any FDA approval of Crystal's generic products shall be no earlier than the expiration date of the '997 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

LLL. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from manufacturing, using, offering for sale or selling Crystal's generic products within the United States, or importing Crystal's generic products into the United States, until the expiration of the '997 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

MMM. The entry of a preliminary and/or permanent injunction, enjoining Crystal and all persons acting in concert with Crystal from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '997 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

NNN. The issuance of a declaration that this is an exceptional case and an award to Plaintiff of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

OOO. An award to Plaintiff of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

PPP. An award to Plaintiff of any further and additional relief that this Court deems just and proper.

ASHBY & GEDDES

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